

Remarks

Applicants and the undersigned reviewed the pending office action carefully before preparing this response. In light of the positions presented herein, in conjunction with the accompanying Request for Continued Examination, this application is believed to be in condition for allowance.

Several claims were rejected under 35 U.S.C. § 103 as obvious in view of Powers. Applicants appreciate the Examiner's concern, but respectfully disagree. As previously stated, it appears the Examiner misconstrued this invention, did not consider it as a whole, and did not take into consideration one or more result-effective variables associated therewith. Applicants established that Powers teaches away from Applicants' invention, and that there is no *prima facie* obviousness.

In response, the Examiner merely restated her position; that is, substitution for hydrogen off the carbon alpha to boron is obvious. However, the Examiner still fails to cite any pertinent reference showing or suggesting such a substitution. In the absence of such a reference, there is no *prima facie* obviousness and Applicants are entitled to full allowance of the subject claims. The sole citation provided by the Examiner supports only methyl substitution for hydrogen in an unrelated compound. Such generalities cannot, without more, be extended from one unrelated chemical system to another.

Interestingly, the same case cited by the Examiner supports the proposition that unexpected properties would be evidence of non-obviousness. Applicants' compounds (of Claims 1-12 and as part of the compositions of Claims 28-34) provide impressive results at least in part attributable to substitution for hydrogen, alpha to boron. Reference is made to data and analyses throughout the present specification, in particular that provided by Table 1 on page 15, comparing the potency of prior art compounds (R_2 is H) with representative compounds of Applicants' invention.

Section 103 requires evaluation of the invention "as a whole." Such evaluation includes comparative data of the sort provided by Applicants in Table 1. Required

analysis of the invention as a whole supersedes arbitrary rules such as those for hydrogen substitution. Data showing improved potency and efficacy of the present compounds shows the prior art fails to teach or suggest substitution alpha to boron. Accordingly, consideration of the invention "as a whole" precludes *prima facie* obviousness on mere structural similarity. See, *In re Langer*, 465 F.2d 896, 175 U.S.P.Q. 169 (C.C.P.A. 1972).

In the alternative, the aforementioned comparative data, in particular that of Table 1, effectively rebuts the Examiner's position. An initial holding of *prima facie* obviousness disappears, and the Examiner must consider all evidence including the data of Table 1 uninfluenced by her earlier decision. See, *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143, 147 (C.C.P.A. 1976). As mentioned above, the Examiner did no more than restate her previous position. It appears Applicants' data, if considered at all, was evaluated only against the Examiner's initial conclusion. Such a procedure is not permitted under Section 103. Without further analysis, it must be concluded that the Examiner's position has been successfully rebutted. Again, the rejection should be withdrawn, with the subject claims allowed to proceed toward issue.

If, for any reason, the obviousness rejection is maintained, it would appear that the motivation to modify the prior art is based on facts within the personal knowledge of the Examiner. Accordingly, pursuant to 37 C.F.R. § 1.104(d)(2), Applicants respectfully request the Examiner provide an affidavit supporting such personal knowledge, with specific reference to the prior art and where that motivation is found.

It should be noted that use of the word "comprising" is not an invitation to read any and all prior art into a claim. Extending the Examiner's rationale, any prior art—no matter how unrelated—could be used to fabricate an obviousness rejection. Here, the issue remains one of Applicants' compounds, with substitution alpha to boron. Without motivation to modify the prior art, there is no *prima facie* obviousness.

Several claims were also rejected under 35 U.S.C. § 112, first paragraph, for lack of written description with regard to the term "heterocyclyl". Again, Applicants appreciate the Examiner's concern, but respectfully disagree. The subject matter of the claims need not be described literally in the specification. It is sufficient that the specification convey clearly to those skilled in the art that an applicant invented the claimed subject matter. Determining whether the written description requirement is satisfied requires reading the specification in light of the knowledge possessed by those skilled in the art. Such knowledge can be established by reference to patents in the field.

A search of the Patent Office database shows no less than 77 patents with "lactamase" in the specification and "heterocyclyl" in the claims. A quick review shows the term defined much as Applicants have done, with representative non-limiting structural or compound examples. In each instance, it appears those skilled in the art knew and understood the claimed subject matter. Here, too, a general definition of "heterocyclyl" provides enough specificity so that one skilled in the art can sufficiently identify the claimed subject matter. Accordingly, this rejection should be withdrawn, with the subject claims allowed to proceed toward issue.

The Examiner also rejected several claims under 35 U.S.C. § 112, first paragraph, as non-enabling for heterocyclyl compounds. Again, Applicants respectfully disagree. The Examiner is reminded that the law does not require an application to be a production blueprint to satisfy the enablement requirement. Rather, it has been long-held that a specification need not describe—and best omits—that which is well-known in the art. The full range of subject matter regarding heterocyclyl compounds is adequately described in the specification, as would be understood by those skilled in the art.

By law, a patent application is presumptively enabled when filed. The Examiner must establish a *prima facie* case of non-enablement; that is, there must be some explanation why there is reason to doubt the objective truth of the statements contained in

the application, supporting such an assertion with acceptable evidence or reasoning. It is well established that enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Whether undue experimentation is needed is not a single, simple factual determination, but rather a conclusion reached by weighing many factual considerations. *In re Wands*, 8 U.S.P.Q.2 1400, 1404 (Fed. Cir. 1988).

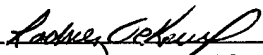
Here, the Examiner's position is supported by nothing more than a rote recitation of the *Wands* factors. A listing of the *Wands* factors is not a determination of facts. Mere recitation does not provide the requisite factual consideration. For instance, the "nature of the invention" factor is applied to the claims with nothing more than Applicants' generic formula. The "state of the prior art" factor is applied with only a short self-evident statement about lactamase inhibitors. Analysis of the "predictability" factor goes no further than a vague, conclusory statement about unpredictability. The Examiner's position regarding the "direction or guidance", "working examples" and "quantity of experimentation" factors completely disregards Schemes 1-3, Tables 1-3, working examples 1-10, 20a-20d, 21a-21c, and the corresponding specification discussion about design and preparation of such compounds.

In light of the foregoing, Applicants respectfully disagree with the Examiner's assessment under § 112, first paragraph. There is no *prima facie* non-enablement. The present specification is enabling for a wide range of compounds comprising heterocyclyl moieties. Even though the subject term is broad, those skilled in the art would understand from a straight-forward reading of the specification how to make and use the subject compounds and compositions. Additional experimentation is expected with any invention. Even considerable experimentation over an extended period is permissible, where as here the specification would guide one skilled in the art how that experimentation should proceed. Accordingly, the specification enables preparation of a

range of compounds commensurate with the term "heterocyclyl". This rejection, too, should be withdrawn, with the subject claims allowed to proceed toward issue.

This application is believed to be in condition for allowance. Consistent therewith, a favorable action is respectfully requested. The Examiner is invited to contact the undersigned by telephone should any issue remain.

Respectfully submitted,



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